K133213

510(k) SUMMARY

H.C. Starck Ceramics GmbH
StarCeram®

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Maureen O'Connell
O'Connell Regulatory Consultants, Inc.
5 Timber Lane
North Reading, MA 01864
Phone: (978) 207-1245
Facsimile: (978) 824-2541

DEC 0 5 2013

Date Prepared: November 6, 2013

Name of Device and Name/Address of 510(k) Owner

StarCeram® Z-Med
StarCeram® Z-Al-Med HD
StarCeram® Z-Al-Med HD Colour
StarCeram® Z-Al-Med-HD Translucent
StarCeram® Z-Med TransColour

H.C. Starck Ceramics GmbH
Lorenz-Hutschenreuther-Str. 81
95100 Selb, Germany

Common or Usual Name

Powder, Porcelain

Classification Name

21 C.F.R. 872.6660

Predicate Devices

StarCeram Z-Med and Z-Al-Med HD (K081263)
ZENO Zr Disc (K112710)

Intended Use / Indications for Use

Dental Blanks made from StarCeram® are indicated for crowns, multi-unit bridges, inlay bridges and all-ceramic restoration. Applications include both anterior and posterior bridges.

Technological Characteristics

Dental blanks made from StarCeram® products are semi finished products made of yttrium stabilized pre-sintered zirconium dioxide for milled production of crowns and bridge framework on commercial CAD/CAM systems or hand-operated copy-milling.

Performance Data

No performance data was required or provided. Biocompatibility and cytotoxicity testing was performed which showed that all versions of the product comply with ISO 10993-1.

Substantial Equivalence

StarCeram® Z-Med and StarCeram® Z-Al-Med HD were previously cleared in K081263. The only change to the cleared products is the additional indication for use related to all-ceramic restoration. All other aspects of the product including physical properties remain unchanged compared to the product cleared in K081263.

Regarding StarCeram® Z-Al-Med-HD Colour, StarCeram® Z-Al-Med HD Translucent, and StarCeram® Z-Med TransColour, these are dental blanks which are fabricated to the desired shape by the user based on the specific needs of the patient. The only difference between these three new products and the two StarCeram® products cleared in K081263 is the exact combination of qualities of zirconium dioxide used in each product. All other physical properties are identical to the StarCeram® products cleared in K081263.

Regarding the ZENO Zr Disc predicate device cleared in K112710, these products are also a group of medical devices which are discoidal shaped and partially sintered dental ceramic materials that are composed of zirconium dioxide. They are also available in various colors, translucencies and thicknesses. These blanks are also processed by the user based on the specific needs of the patient. The ZENO Zr Disc products are provided in 7 colors and a variety of thicknesses ranging from 10 to 25 mm which is the exact range of thicknesses offered for the StarCeram® products.

The only difference between the StarCeram® Z-Al-Med-HD Colour, StarCeram® Z-Al-Med HD Translucent, and StarCeram® Z-Med TransColour products and the StarCeram® products cleared in K081263 is the exact formulation of zirconium dioxide used. These differences have been addressed by performing biocompatibility testing which was provided in the 510(k) and showed that all versions of the product were found to be biocompatible. Therefore, the differences do not affect the safety or effectiveness of the products.

Similarly, when comparing the StarCeram® products to the ZENO Zr Disc predicate device cleared in K112710, the differences are the exact shapes of blanks offered and the exact formulation of zirconium dioxide utilized in each version of the product. The differences in the exact shapes of blanks available does not affect the safety or effectiveness of the product as the user chooses the blank that meets the needs of the patient and then processes the blank to the shape needed. Regarding the exact formulation of zirconium dioxide utilized in the StarCeram® products and the ZENO Zr Disc products, both product lines use a variety of formulations to achieve a range of colors and translucencies. These differences have been addressed in the biocompatibility testing which was provided in the 510(k) which showed that all versions of the products were found to be biocompatible. Therefore, the differences do not affect the safety or effectiveness of the products.

Therefore, StarCeram® products are substantially equivalent to the identified predicate devices because they have the same intended use and technological characteristics including materials, application process and biocompatibility.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 5, 2013

H.C. Starck Ceramics GmbH
C/O Ms. Maureen O'Connell
Regulatory Consultant
O'Connell Regulatory Consultants, Inc.
5 Timber Lane
North Reading, MA 01864

Re: K133213
Trade/Device Name: StarCeram
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: November 6, 2013
Received: November 7, 2013

Dear Ms. O'Connell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer -S for

Erin I. Keith M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K133213

Indications for Use Statement

510(k) Number (if known):_____

Device Name: StarCeram®

Indications for Use:

Dental Blanks made from StarCeram® are indicated for crowns, multi-unit bridges, inlay bridges and all-ceramic restoration. Applications include both anterior and posterior bridges.

Prescription Use ___X__ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ _____ _____ _____
_____ Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner DDS #14 Mary S. Runner -S 2013.12.04 13:44:57 -05'00'